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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/121,849	07/24/98	GARFIELD R	SCH1237DI

HM22/0104
MILLEN WHITE ZELANO AND BRANIGAN
ARLINGTON COURTHOUSE PLAZA 1
2200 CLARENDON BOULEVARD
SUITE 1400
ARLINGTON VA 22201

EXAMINER	
LILLING,H	
ART UNIT	**PAPER NUMBER**
1651	16

DATE MAILED: 01/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/121,849	GARFIELD ET AL
Examiner	**Group Art Unit**
DR. HERBERT J. LILLING	1651

☒ Responsive to communication(s) filed on *Nov 21, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *ONE* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-30 and 32-35* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-30 and 32-35* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

1. The request filed on November 21, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/121,849 is acceptable and a CPA has been established.

2. Receipt is acknowledged of the prior art information disclosure statement filed December 19, 2000.

3. Claims 1-30 and 32-35 are present in the instant application. Claim 31 has been cancelled.

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-13, 22-27 and 32-33 drawn to a method of treating preeclampsia with an effective amount of a pharmaceutical composition comprising (a) a progestin (b) a nitric oxide synthesis substrate, a nitric oxide donor or both and (c) at least one of the ingredients as noted by Claim 14, classified in Class 514, numerous subclasses depending upon the specific ingredients.

II. Claims 14-21, 28-30 and 34, drawn to a pharmaceutical composition containing at least the following three components (a) a progestin (b) a nitric oxide synthesis substrate, a nitric oxide donor or both and (c) at least one of the ingredients as noted by Claim 14, classified in Class 514, numerous subclasses depending upon the specific ingredients of (b) or (c).

III. Claim 35, drawn to a pharmaceutical composition comprising the following two components (a) a progestin (b) a nitric oxide synthesis substrate, a nitric oxide donor or both , classified in class 514, subclass 314.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions II/III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product compositions can be used in a materially different process of using that product, e.g. control high blood pressure.

Inventions III does not require the specifics of Invention II and are patentably distinct from each other.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter and the search required for one invention is not required for the other invention, thusly the restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

I. Whereby the composition and processes contain

a. nitric oxide synthase substrate

b. nitric oxide donor

and

whereby the nitric oxide donor is selected from the group consisting of:

bi. sodium nitroprusside

bii. nitroglycerin

biii. glyceryltrinitrate

biv. SIN-1

bv. isosorbidmononitrate or isosorbiddninitrate

c. both a and b.

II. Whereby compositions and processes contains

i. cyclooxygenase inhibitor

ii. a compound containing PGI_2-agonistic and TXA_2-inhibiting properties,

iii. compound possessing TXA_2-antagonistic and PGl_2-memetic activities

and whereby the memetic is

iiia. iloprost

iiib. cicaprost

iv. TXA_2 antagonist

v. a thromboxane (TXA_2) inhibitor

vi. more than one of the above-please specify

vii. composition or processes absent i-vi.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 14 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit 1651
January 02, 2001

HERBERT J. LILLING
PATENT EXAMINER
GROUP 1600 ART UNIT 1651